**Minutes of Meeting**

**Alabama Medicaid Agency**
**Pharmacy and Therapeutics Committee**

**October 27, 2004**
**1:00 p.m.**

Attendees: Richard Freeman, Chair; Jackie Feldman, David Herrick, A.Z. Holloway, Mary McIntyre, Ben Main, Garry Magouirk, Jimmie Clark, Sheri Boston, Louise Jones, Janelle Sheen

Absent: Dane Yarbrough

(1) OPENING REMARKS
Richard Freeman called the meeting to order at 1:06 p.m. and asked that all cell phones and pagers be placed in the off position.

(2) Chairman Freeman asked if there were corrections to the minutes from the August P&T meeting. There were no additions or corrections recommended in the proposed minutes. Dr. Garry Magouirk motioned to approve the minutes and Dr. A.Z. Holloway seconded the motion.

(3) Louise Jones gave the pharmacy program update:

The Health Information Design (HID) contract has been extended through October 31, 2005, and has the potential to run for a total of three years. The contract is just moving into its second year.

The electronic prior authorization program is moving forward and scheduled for a December 1, 2004 implementation. This program will lessen the volume of paperwork (eliminate 40% of the current prior authorizations) needed for medical justification, for physicians and their staff. The program is being provided by HID and is being offered for no extra fee.

Blue Cross and Blue Shield of Alabama's InfoSolution PDA software program is on target for implementation also on December 1, 2004. The PDA devices will be available to the agency's Patient First providers, and to other providers for a nominal fee. The specifics on the cost of the PDA to providers is still being detailed. This technology will allow physicians to have access to a patient's medical and pharmacy claims history (Medicaid and BCBS claims data), and will be a useful tool to pinpoint patients using multiple physicians and/or pharmacies.

The agency is working to compile savings results for the brand limit that was put in place July 1, 2004. Ms. Jones commented she has been given additional staff that will help with this evaluation. Dr. Jackie Feldman commented that the Agency should have a mechanism in place to monitor and track recipient hospitalizations and deaths, as a way to determine if any of the limits the Agency has put in place are causing a negative impact on the recipient population. Dr. Magouirk discussed the difficulty in tracking cause of death in his practice. A.Z. Holloway added his concern that some of the programs the Agency has implemented aren't saving money if pharmacy costs are decreasing and medical costs (hospitalizations) are increasing. He commented the Agency should have a way to track any negative impact a program may have on recipients. Louise Jones responded that the Agency is aware of these issues and is working on evaluating the impact of the recently implemented programs. Mary McIntyre reported there is no specific mechanism in place to review cause of death in the population. Dr. McIntyre and Louise Jones commented that no data to date has shown there has been a negative outcome on patient care as a result of limits recently put in place. The Agency hopes to have data on recently implemented programs out in the next couple of weeks. Ms. Jones announced she hopes to send out an informative e-mail update to the P&T members between P&T meetings. Ben Main questioned where the budget stood and Louise commented that as of October 2004 the pharmacy program is currently $2 million dollars under budget, with PDL savings at $42 million. Louise also added the therapeutic duplication edit has been very successful.

Louise announced that she will draft/complete an invitation to bid (ITB) for clinical services, PDL support, and supplemental rebates, within the next month. ACS-Heritage Information Systems will continue to support the PDL through January 31, 2005. The new vendor will begin either in February or March of 2005.

Ms. Jones announced the Agency has been working with the pharmaceutical industry. One result of discussions is that at the end of the P&T meeting, the results of the total member ballots will be announced. This is not a final decision, as the Committee is an advisory panel. The results of the ballots may change, especially as some recommendations may indicate the Agency work with the manufacturers of the drugs in the class on a preferred agent. Louise made sure there was no confusion among audience members on this process. It was also announced that the time period allowed for manufacturer presentations was changed from three minutes to five minutes.

It was announced that the Alabama Medicaid Agency has been working with HealthWatch Technologies, on audits and has collected approximately $1 million dollars (from pharmacy providers) as a result of the audits so far. Laboratory services will be the next focus of the audits. HealthWatch Technologies is being paid on a contingency basis, so their services are of no additional cost to the Agency.

Finally, Louise discussed the timeline for the P&T Committee meetings. The timeline is posted on the Alabama Medicaid Agency website, and this should be checked by manufacturers with regard to deadlines. No exceptions will be made for manufacturers who do not meet deadlines as established on the posted timeline. Any supplemental contracts from manufacturers received after the established deadline will be considered in the following quarter.

(4) Louise Jones introduced and welcomed the P&T committee, along with two new members, Jimmie Clark, M.D. and Sheri Boston, R.Ph.

(5) Elections for Committee Vice Chair

The October meeting was Dr. Freeman's last meeting as the committee Chair. Dr. Magouirk will become the committee Chair at the January 2005 meeting. Louise Jones commented the only eligible committee member for the Vice Chair position was Jimmie Clark, since this member must be a physician with two years of service left on the committee. Dr. Clark accepted the nomination as Vice Chair.

(6) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews):

Ms. Sheen began discussion by explaining the anti-infective reviews were divided due to the significant amount of clinical data for review by committee members. The additional anti-infective classes will be reviewed at the January 2005 meeting. Janelle reported no anti-infective classes would be implemented on the PDL until all of the classes are completed at the January meeting.

Ms. Sheen also commented on Alabama ACT 2003-297 of the legislature that clearly states all antiretrovirals are specifically excluded from review for the PDL. She stated that even though some of the anti-infective classes being reviewed contained medications that can be used for opportunistic infections in HIV patients, these AHFS classes and drugs are not classified as anti-retrovirals and are still subject to review for the PDL.

The pharmacotherapy reviews began at approximately 1:20p.m. Five-minute verbal presentations were made on behalf of some pharmaceutical manufacturers. The drugs with manufacturer representatives who spoke on their behalf are listed below prior to each therapy class description. There were a total of seven manufacturer presentations at the meeting.

Section I. Anti-infectives

**Anthelmintics (AHFS Class 080800)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Ms. Sheen began the Anti-infective reviews with the Anthelmintics. She stated there are six drugs in this class including albendazole, ivermectin, mebendazole, praziquantel, pyrantel, and thiabendazole. Pyrantel pamoate is available for self-treatment over-the-counter, while mebendazole tablets are available in a generic formulation. Janelle commented that although helmintic infections are not highly endemic in the United States, they can be found in populations in southern states, immigrants and travelers to endemic areas, institutionalized patients, preschool children, and immunocompromised patients. The treatments of choice for ascariasis includes mebendazole and pyrantel pamoate, while pinworm infection can be treated with mebendazole, pyrantel pamoate, or alendazole. Dosing for agents in the class depends on the infection being treated, as most are given as single doses, or for brief durations. Mebendazole and pyrantel can be used to treat pinworm, whipworm, roundworm, and hookworm infections, which are the more common helmintic infections found in the United States, and these are the drugs of choice for these conditions. Other drugs in the class (albendazole, ivermectin, praziquantel, and thiabendazole) are used to treat less common helmintic infections and should be available for special needs/circumstances through the prior authorization process. Janelle concluded that mebendazole and pyrantel pamoate offer clinical advantages when used for their treatment indications. These agents are available OTC and as generics. The remaining anthelmintic drugs in the class are comparable to each other and to the generics and OTC products and offer no significant clinical advantage over other alternatives in general use. No brand anthelmintic was recommended for preferred status. There was no further discussion.

Richard Freeman asked the Board to mark their ballots.

**Aminoglycosides (AHFS Class 081202)**
<u>Manufacturer comments on behalf of these products:</u>
Tobi

Janelle Sheen discussed the six aminoglycosides, five of which are parenteral and two are oral drugs, in the review. Only tobramycin is available as an oral inhalation and gentamicin is indicated for intrathecal administration. These agents are largely used during hospitalization, through intravenous administration. Janelle explained the aminoglycosides are active against gram-negative and gram-positive bacteria and are used for serious infections including septicemia, bone and joint infections, skin and soft-tissue infections, respiratory tract infections, urinary tract infections, and postoperative and intra-abdominal infections. These agents have synergistic activity when used together with extended-spectrum

penicillins with antipseudomonal activity. Gentamicin is the most often used aminoglycoside, while tobramycin is the aminoglycoside of choice against *Ps. aeruginosa*, and amikacin is a good choice for bacteria resistant to other aminoglycoside agents. Janelle reported that at least one formulation of every aminoglycoside antibiotic is available as a generic formulation, although tobramycin oral inhalation is not. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand aminoglycoside was recommended for preferred status.

Dr. Jackie Feldman questioned whether the tobramycin oral inhalation could be covered through prior authorization and Janelle and Dr. McIntyre concluded it would be available through that process. There was no further discussion.

Richard Freeman asked the Board to mark their ballots.

**Antifungal Agents (AHFS Class 081400)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the antifungals, including the oral and injectable agents. She described these agents can be used for a range of fungal diseases, from opportunistic infections, to neutropenia, to cryptococcemia, candidiasis, and organ transplantation. Amphotericin B agents, azole antifungals, and echinocandins are therapy options for invasive candidiasis. Azole antifungals are good therapy options for mucocutaneous candidiasis. Fluconazole and itraconazole are appropriate therapies for patients at risk for invasive candidiasis. Terbinafine and itraconazole are treatments of choice for onychomycosis but are associated with an FDA issued Public Health Advisory due to issues with congestive heart failure (itraconazole) and serious liver problems. Itraconazole and ketoconazole both have black box warnings pertaining to drug interactions and there are contraindications as a result of certain drug interactions. Janelle explained the efficacy of the amphotericin B agents is similar, although the lipid formulations are less renal toxic. Clinical evidence suggests greater efficacy of terbinafine versus itraconazole, however, treatment is often non-medical, and therapy should be reserved for patients with predisposed foot complications.

Because the amphotericin B agents have limited use in outpatient treatment, these agents should be available through medical justification with prior authorization. Therefore, the brand amphotericin B agents within the class reviewed are comparable to each other and to the generics in the class and offer no significant advantage over alternatives in general use.

Because the use of terbinafine and itraconazole for onychomycosis should be reserved for patients with predisposed foot complications, there is not a role for these agents in general use. Due to the generic availability of fluconazole,

ketoconazole, nystatin, and griseofulvin, all brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use.

The remaining agents in the class: caspofungin, flucytosine, IV itraconazole, and voriconazole have indications for serious, invasive infections, and use of voriconazole and caspofungin is indicated in those with disease refractory to, or intolerant to other therapies. Therefore, these agents should be made available through medical justification through the prior authorization process. The brands of caspofungin, flucytosine, IV itraconazole, and voriconazole are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. A.Z Holloway confirmed whether the agents for onychomycosis would be available through prior authorization for severe cases. Dr. McIntyre confirmed that they would through medical justification.

Richard Freeman asked the Board to mark their ballots. A one-minute recess was held at 1:50p.m.

**Cephalosporins (AHFS Class 081206)**
Manufacturer comments on behalf of these products:
Omnicef
Spectracef
Suprax

Janelle Sheen commented that research on Suprax revealed the drug had been discontinued, however, per the manufacturer presentation, there is a Suprax suspension available. Janelle asked the members to make that notation.

Janelle discussed that the cephalosporins are divided into three generations, with the first generation agents most active against gram-positive aerobes, and third-generation agents most active against gram-negative aerobes, including Enterobacter, Pseudomonas, and some anaerobic organisms. All of the oral third generation agents, except for cefditoren, are available as suspensions. First and second generation drugs are also available in a suspension formulation. There are nine drugs in the review that are injectables, two of these are also available in oral formulations. Generic formulations are available for first, second, and third generation cephalosporins.

In looking at indications, cephalexin is currently the only cephalosporin with indications for bone infections caused by staphylococci or *Proteus mirabilis.* Cephalexin is also the only cephalosporin with indications for genitourinary tract infections including acute prostatitis caused by *E. coli*, *P. mirabilis*, and Klebsiella species. Cefpodoxime is currently the only cephalosporin approved for ano-rectal infections. Cefuroxime is currently the only cephalosporin approved for Lyme disease. All of these drugs are available as generic formulations. In

looking at efficacy and safety, not all cephalosporins have been directly compared to all other cephalosporins for certain indications. Studies presented in the review show comparable efficacy of some of the cephalosporins for the treatment of urinary tract infections, skin structure infections, and upper and lower respiratory tract infections. Data also demonstrates a similar safety profile between cephalosporins, particularly within generations. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer significant clinical advantage over other alternatives in general use. No brand cephalosporin was recommended for preferred status.

A.Z Holloway commented that he uses one-time Rocephin IM for gonococcal disease in patients. Janelle Sheen responded that the patent for Rocephin is set to expire in July 2005 and at that time a generic would likely become available. She also explained that the drug would be available through prior authorization until that time. Other members commented on the importance of having Rocephin available and A.Z. Holloway motioned to amend the recommendation that Rocephin be preferred until a generic formulation becomes available. Dr. Feldman seconded the motion. The motion by Dr. Holloway also included that at least one oral third generation cephalosporin oral suspension be preferred.

Richard Freeman asked the Board to mark their ballots.

**Single Entity Misc. B-Lactam Antibiotics (AHFS Class 081207)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the single entity misc. B-lactam antibiotics. These antibiotics offer enhanced spectrum of activity with low toxicities. Among the single entity agents in this class, loracarbef is the only oral agent, while cefoxitin is the only single entity agent available as a generic formulation. With respect to spectrum of activity, the drugs were compared. Aztreonam offers gram-negative aerobic coverage only. Cefotetan and cefoxitin have similar spectrums, however, cefotetan can be dosed less frequently. Ertapenem covers a wide variety of gram-positive and gram-negative organisms, and some anaerobic organisms. Loracarbef offers coverage similar to the second generation cephalosporins, with gram-positive and gram-negative coverage. Meropenem is a broad spectrum antibiotic with a spectrum similar to imipenem.

The single entity misc. b-lactam antibiotics would not routinely be first-line therapies on an outpatient basis. Aztreonam is an alternative to the use of aminoglycosides. Studies have shown ertapenem to be comparable to piperacillin/tazobactam and ceftriaxone, depending on the use. Specifically, loracarbef has a similar spectrum to that of cefaclor, which is available as a generic formulation. Studies have shown loracarbef to have similar efficacy compared to doxycycline, norfloxacin, clarithromycin, and cefdinir. Finally, it

was mentioned that meropenem is a good antibiotic choice for empiric therapy in polymicrobic infections or in multi-drug resistant infections. With the exception of loracarbef, the single entity b-lactam agents are given to hospitalized patients, due to the serious nature of the indications of the agents. Therefore, although there may be some clinical advantage to the drugs in this class in special needs/circumstances, there is not a role for these agents in general use. All brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand single entity misc. b-lactam antibiotic is recommended for preferred status. There was no further discussion in this class made by committee members.

Richard Freeman asked the Board to mark their ballots.

**Combination Misc. B-Lactam Antibiotics (AHFS Class 081207)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the single combination b-lactam antibiotic, imipenem/cilastatin. The cilastatin component of the agent is added to imipenem, due to its ability to inhibit dehydropeptidase-1, an enzyme found in the renal tubule border that metabolized imipenem. Without cilastatin, imipenem is rapidly metabolized and is toxic to the proximal tubule. Cilastatin itself has no antibacterial activity. Janelle explained that imipenem/cilastatin has a broader spectrum of activity than other b-lactam antibiotics and has 9 indications, from septicemia to polymicrobic infections, to bone and joint infections and endocarditis. Clinical efficacy data suggests that imipenem/cilastatin and meropenem are similar in efficacy and safety. Therefore, imipenem/cilastatin, like other injectable beta-lactam antibiotics, would not routinely be used as a first-line therapy on an outpatient basis, and is not an agent that would carry a role in general use. All brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand combination misc. b-lactam antibiotics was recommended for preferred status. There was no further discussion on behalf of the committee.

Richard Freeman asked the Board to mark their ballots.

**Chloramphenicol (AHFS Class 081208)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the use of chloramphenicol and stated it is a broad spectrum agent with coverage of a wide-range of gram-positive, gram-negative, and anaerobic bacteria. The drug also covers Chlamydia and Rickettsia and is only available as an injection. Chloramphenicol is also available in a generic

formulation. The drug is indicated for infections in which less potentially dangerous drugs are ineffective or contraindicated, and acute infections. It is the drug of choice for the treatment of typhoid fever. Chloramphenicol use is limited to hospitalized patients and is associated with a black box warning due to blood dyscrasias. As a result of chloramphenicol's limited use and black box warning, there is not a role for chloramphenicol in general use. All brands within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand of chloramphenicol is recommended for preferred status. The committee had no further discussion on chloramphenicol.

Richard Freeman asked the Board to mark their ballots.

**Single Entity Penicillins (AHFS Class 081216)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the single entity penicillins and commented that there were ten single entity penicillins, including natural penicillins, aminopenicillins, and extended-spectrum penicillins. Generic formulations are available for all of the single entity penicillins except for carbenicillin and ticarcillin. Penicillins continue to be the drugs of choice or alternative choices for therapy of a wide range of bacterial. Methicillin is the drug of choice for sensitive strains of staphylococcal infections. Amoxicillin and ampicillin are first line agents for enterococcus, including urinary tract infections caused by enterococcus faecalis. Streptococcal infections including viridans group A, B, C, and G can be treated empirically with penicillin G or ampicillin. Anthrax can be treated with doses of penicillin G or amoxicillin. All oral, single entity natural penicillins, penicillinase-resistant penicillins, and aminopenicillins in the class are available in generic formulations and are available to recipients. The extended-spectrum penicillins may have a use for more serious infections requiring hospitalization, but there is not a role for these agents in general use. The extended-spectrum agents should be available for special needs/circumstances that require medical justification through prior authorization. Therefore, no brand single entity penicillin was recommended for preferred status. Dr. Feldman questioned the turn-around time with prior authorizations. Multiple committee members commented they have not had problems getting an authorization in a timely manner. There was no further discussion from committee members.

Richard Freeman asked the board to mark their ballots.

**Combination Penicillins (AHFS Class 081216)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen presented the four combination penicillin agents, one being an oral agent, amoxicillin/clavulanate. She explained that gram-negative bacteria such as *E. coli*, Acinetobacter spp., and *P. aeruginosa* may be treated with combinations of penicillins. The penicillin combinations act synergistically to expand the spectrum of activity of these antibiotics against strains of beta-lactamase producing organisms. At this time there is one oral and one injectable combination penicillin available as a generic (amoxicillin/clavulanate and ampicillin/sulbactam). Augmentin XR and Augmentin ES 600 are not available in generic formulations. They both have limited indications. Augmentin ES is only indicated for otitis media and the XR is only indicated for community acquired pneumonia. Within this class, amoxicillin/clavulanate is the only combination penicillin antibiotic with a role in general use, and a generic formulation is available. The other combination injection penicillins are used for more serious infections typically requiring hospitalization. These drugs should be available for special needs/circumstances that require medical justification through prior authorization. Therefore, all brand products within the class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand combination penicillin antibiotic was recommended for preferred status. There was no further discussion from committee members.

Richard Freeman asked the board to mark their ballots.

**Tetracyclines (AHFS Class 081224)**
Manufacturer comments on behalf of these products:
Periostat

Janelle Sheen began discussion in this class with an overview of the five agents. All oral tetracyclines are available with generic formulations. Doxycycline is the preferred therapy for rickettsial tick borne disease and Lyme disease. It is also useful for sexually transmitted diseases including syphilis, Chlamydia, pelvic inflammatory disease, and epididymitis. Janelle commented that dosing data on Periostat had been omitted from the dosing table in the review, but a handout of the dosing information was provided to each member for easy addition into the review binder. Janelle also verbally described the dosing of Periostat as 20mg given twice daily, as an adjunctive treatment to scaling and root planning in periodontitis. Janelle further commented that tetracycline is used in the treatment of peptic ulcers (H. pylori) and several of the agents have specific uses for non-infectious diseases, such as demeclocycline for hyponatremia. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and offer no significant clinical advantage over other alternatives in general use. No brand tetracycline was recommended for preferred status. Dr. Clark asked if Periostat would be available through prior authorization and was ensured it would be, due to the limited use of the drug in the population. Dr. McIntyre added that a generic was available for doxycycline and that she has seen it used following dental scaling. A.Z. Holloway also questioned use of Periostat

and Dr. McIntyre explained that the Alabama Medicaid Agency does not cover dental for adults so this agent is considered a "slippery slope". Dr. Freeman commented that he has seen multiple cases this year of Rocky Mountain Spotted Fever and that doxycycline was the drug of choice.

Richard Freeman asked the board to mark their ballots.

**Single Entity Nucleosides and Nucleotides (AHFS Class 081832)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen described this class of eight agents, used for herpes simplex virus (HSV), Varicella Zoster Virus (VZV), cytomegalovirus (CMV), chronic hepatitis B and C, and respiratory syncytial virus (RSV). Three agents (ganciclovir, acyclovir, and cidofovir) are injectables. Ganciclovir and acyclovir are available in a generic formulation. Ribavirin can be aerosolized for the treatment of RSV. With the exception of acyclovir, famciclovir, and valacyclovir, the agents in this class have limited and specific indications. This makes the role of these agents in general use minimal. The efficacy of acyclovir, famciclovir, and valacyclovir against HSV and VZV infections are similar based on comparative studies. CDC guidelines suggest all 3 agents for treatment and suppression of genital herpes. Acyclovir is the only agent recommended by the AAP for the treatment of chickenpox in patients at risk for more severe disease.

Comparative studies of the agents in this class for CMV have shown similar results. Oral ganciclovir is indicated only for maintenance therapy of CMV retinitis following induction . Cidofovir is an effective therapy option as well, for CMV retinitis, however, comparative data for it versus ganciclovir or valganciclovir are lacking. Nephrotoxicity is a major adverse event limiting the duration of its treatment, however, cidofovir is an alternative in patients who do not respond to ganciclovir or valganciclovir.

Oral ribavirin is indicated in combination with interferons for chronic hepatitis C. Although aerosolized ribavirin demonstrated good in vitro activity against RSV, clinical efficacy data are conflicting and due to potential toxicities, ribavirin is not generally used.

Adefovir, lamivudine, and interferon-alfa are all first-line options for chronic hepatitis B. Adefovir is useful in patients with lamivudine resistance. All brand antiherpetic agents in the class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. Additionally, the treatments for CMV, HBV, and RSV are not within the scope of general use and should be available for their indicated special needs/circumstances via medical justification through the prior authorization process. Therefore, no brand single entity antiviral

nucleoside/nucleotide is recommended for preferred status. No further discussion was made by board members.

Richard Freeman asked the board to mark their ballots.

**Misc. Antivirals (AHFS Class 081892)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed foscarnet injection as the only drug in this class. Foscarnet inhibits the viral specific DNA polymerases and reverse transcriptases and is indicated for use in immunocompromised patients with CMV retinitis, relapsed CMV retinitis, and mucocutaneous acyclovir-resistant HSV infections. Foscarnet is not associated with major myelosuppressive toxicity, like ganciclovir is. Foscarnet is associated with a black box warning due to renal impairment. Frequent monitoring of serum creatinine and dose adjustments are often necessary, as seizures related to alterations in plasma minerals and electrolytes have occurred. Foscarnet and cyclosporine do interact in a level 1 drug interaction, due to increased risk of renal failure. Foscarnet and quinolones can increased the risk of seizure. Foscarnet should be reserved for approved indications or infections resistant to other antiviral therapies. Use is limited to hospitalized patients where therapy can be given and monitored appropriately. Due to foscarnet's limited indications and the black box warning, the drug should be available for special needs/circumstances that require medical justification through the prior authorization program. Therefore, all brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand of foscarnet was recommended for preferred status. Dr. Clark commented whether this agent should be excluded from the PDL due to its use in HIV patients, and Janelle clarified that the agent can be used in non-HIV immunocompromised patients as well and it is not classified as an antiretroviral. Dr. McIntyre clarified that the legislative rule specifically applied to antiretrovirals and antipsychotics.

Richard Freeman asked the board to mark their ballots.

**Amebicides (AHFS Class 083004)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the three drugs presented in Table 1 of the review. Tinidazole was recently approved and is not yet eligible for review, but will be reviewed in the future. At this time, there are no Iodoquinol products in the Alabama Medicaid drug file database. Paromomycin has a spectrum of activity similar to neomycin, but the drug is considered a luminal or contact amebicide. Paromomycin is available in a generic formulation. It is not absorbed into

systemic circulation, so use is limited to infection within the intestine. Combination extralesional infections should be treated with another anti-infective such as metronidazole, followed by a course of paromomycin to eradicate the luminal infection. Paromomycin is indicated for a range of parasitic infections and hepatic coma. Iodoquinol is only approved for acute and chronic intestinal amebiasis. No studies have directly compared paromomycin to iodoquinol in the treatment of intestinal amebiasis. Therefore, all brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand amebicide was recommended for preferred status. No further discussion was made by committee members.

Richard Freeman asked the board to mark their ballots and called for a ten minute recess. The break was instituted at 3:02p.m. and the meeting resumed at 3:15p.m.

**Single Entity Antimalarials (AHFS Class 083008)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the eight single-entity anti-malarial agents. Chloroquine is also available as an injection and all of the single entity agents are available in generic formulations except for pyrimethamine (Daraprim). The incidence of malaria in the U.S. largely comes from travelers returning from malaria endemic countries of the world, although the risk of re-introduction of the disease is a constant risk. Maria in humans is caused by one of four protozoan species of the genus Plasmodium. All are transmitted by the bite of an infected female Anopheles mosquito. The single entity agents in this class are used for prophylaxis or treatment of one of the four malarial causing species. The CDC recommended agents for malaria include chloroquine, hydroxychloroquine, mefloquine, primaquine, quinine, and the combination atovaquone-proguanil. All of the single entity agents have generic equivalent products on the market. Resistance to antimalarial drugs has developed and treatment choices should be based on the latest information on resistance patterns for specific geographic areas. Therefore, all brand products within the single-entity antimalarial agents are comparable to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand single entity antimalarial product was recommended for preferred status. No further discussion was made by committee members.

Richard Freeman asked the board to mark their ballots.

**Combination Antimalarials (AHFS Class 083008)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen commented that there are two combination antimalarial agents: atovaquone/proguanil and pyrimethamine/sulfadoxine. Both agents have the same indications: for prophylaxis and treatment of malaria caused by Plasmodium falciparum. Clinical comparative studies show both combination agents to be highly effective, while there are no significant differences between the agents in terms of fever, parasite clearance time, and cure rates. Therefore, all brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant advantage over other alternatives in general use. No brand combination antimalarial agent is recommended for preferred status. No further discussion was made by the committee.

Richard Freeman asked the board to mark their ballots.

**Misc. Antiprotozoals (AHFS Class 083092)**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the misc. antiprotozoals that typically effect individuals in developing countries where sanitation is poor. Protozoal infections may have a higher prevalence in immunocompromised individuals. Examples of protozoal infections include cryptosporiodiosis, giardiasis, amebiasis, balantidiasis, trichomoniasis, and pneumocystis carinii pneumonia. There are six agents in this class, and furazolidone is not available at this time. Metronidazole and pentamidine (Pentam 300) are available as generics. The drug of choice for cryptosporiodiosis in non-HIV patients is nitazoxanide, while metronidazole is the treatment of choice for giardiasis and trichomoniasis. For pneumocystis carinii pneumonia, the drug of choice is trimethoprim/sulfamethoxazole. The primary role of the drugs in this class, as pertinent to general use in the population, is for the treatment of giardiasis, amebiasis, balantidiasis, and trichomoniasis. Metronidazole is the agent in this class indicated for these infectious diseases. Therefore, all brand anti-protozoal agents in the class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. Additionally, the therapies for cryptosporiodiosis and pneumocystis carinii pneumonia are not within the scope of general use in the population and should be available for their indicated special needs/circumstances via medical justification through the prior authorization process. No brand antiprotozoal agent is recommended for preferred status. No further discussion was made by members.

Richard Freeman asked the board to mark their ballots.

(7) NEW DRUG REVIEWS (Refer to the web for full text reviews): Section II.

**Estradiol/levonorgestrel (Climara Pro), AHFS Class 681604**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle sheen presented a brief overview of the estradiol/levonorgestrel patch. This patch is the second approved and available combination estrogen/progestin transdermal system. Janelle reminded members the recommendations for hormone replacement therapy are for the use in the management of vasomotor symptoms, using the lowest dose for the shortest duration. Estrogens should not be used for prevention of cardiovascular disease, per the results of the Women's Health Initiative study, spring 2004. The estradiol/levonorgestrel patch is indicated for women with an intact uterus, for the treatment of moderate to severe symptoms associated with menopause. The patch is dosed at one patch once weekly for 28 days, and is only available as 0.045mg estradiol/0.015mg levonorgestrel per day. The clinical efficacy of the combination estrogen products is similar. Therefore, all brand estrogen combination products are comparable to each other and to the generics and offer no significant clinical advantage over other alternatives in general use. No brand combination estrogen product was recommended for preferred status. Dr. Feldman commented on the progestin dose in this patch and compared it to that in the other available combination patch (Combipatch). Sheri Boston added there was a difference in the two combination patches with respect to dosing; estradiol/levonorgestrel is applied once weekly, where the other is applied twice weekly. Dr. Feldman also commented on better compliance with the once weekly patch. Janelle explained the results of a study that looked at once weekly versus twice weekly transdermal patch administration. The study found similar blood levels between the two patches. Janelle also reminded members that convenience of dosing is not a clinical advantage unless it also adds greater clinical efficacy of the drug. Dr. Freeman commented on a writing error in the conclusion of this review where estradiol/norethindrone should have read estradiol/levonorgestrel patch comes as a single formulation. The committee was asked to note the correction.

Richard Freeman asked the board to mark their ballots.

**Fluoxetine/olanzapine (Symbyax), AHFS Class 28104**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen presented the clinical data for fluoxetine/olanzapine. This combination features both an antidepressant and a antipsychotic. Its indication is for the treatment of depressive episodes associated with bipolar disorder. Effectiveness for maintaining antidepressant response in this population beyond eight weeks has not been established in controlled clinical studies. In premarketing studies, 10% of patients receiving the combination discontinued treatment due to adverse events, compared with 4.6% with placebo. The adverse event profile for the combination product was similar to that of olanzapine monotherapy but included higher rates of nausea and diarrhea. The combination is dosed once daily, generally in the evening, beginning with the 6mg olanzapine/25mg fluoxetine capsule. Safety of doses above 18mg/75mg has not been evaluated in trials. No clinical advantage of the combination product over

co-administration of the two ingredients separately has been demonstrated. Therefore, olanzapine/fluoxetine combination (Symbyax) is comparable to the other brands in this class and to the generics and OTC products in the class and offers no significant advantage over other alternatives in general use. Dr. Feldman commented she didn't feel this combination drug was appropriately classified as an antidepressant, but it may offer some benefit for patients with manic depression, and possibly with compliance. She added there is limited clinical data on fluoxetine/olanzapine and felt comfortable with the recommendation made.

Richard Freeman asked the board to mark their ballots.

**Paroxetine mesylate (Pexeva), AHFS Class 281604**
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed that Pexeva is a new salt form of the selective serotonin reuptake inhibitor paroxetine. Pexeva is paroxetine mesylate whereas Paxil is paroxetine hydrochloride. Paroxetine mesylate is considered to be bioequivalent to paroxetine hydrochloride, but is not AB rated to paroxetine HCl due to the difference in salt form. The FDA did not require clinical trials for the approval of paroxetine mesylate due to bridging toxicology and pharmacokinetic studies, combined with existing data and published literature regarding the safety and efficacy of paroxetine HCl. Paroxetine mesylate is approved for major depressive disorder, obsessive compulsive disorder, and panic disorder. The drug is dosed once daily, and is available in 10, 20, 30, and 40mg tablets. Efficacy data for paroxetine mesylate is the same as that found in the package labeling for paroxetine HCl. The drug appears to be similar in efficacy and has comparable outcomes as compared to other selective serotonin reuptake inhibitors. Therefore, paroxetine mesylate is comparable to the other brands in this class and to the generics and OTC products and offers no significant clinical advantage over other alternatives in general use. No brand of paroxetine mesylate (Pexeva) was recommended for preferred status. No further discussion was made by members of the board.

Richard Freeman asked the Board to mark their ballots.

**Tiotropium (Spiriva), AHFS 120808**
Manufacturer comments on behalf of these products:
Spiriva

Janelle Sheen discussed the use of tiotropium, as a long-acting respiratory agent derived from ipratropium. The drug is a nonselective muscarinic antagonist of M1, M2, and M3 receptors and has a greater affinity for these receptors as compared to ipratropium. Tiotropium is dosed once daily and is available as a dry powder inhalation. Tiotropium is indicated for the long-term once-daily,

maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. In efficacy studies, tiotropium versus ipratropium improved FEV1 trough, with a decline of 30ml from baseline ($p<0.001$). Tiotropium decreased exacerbations, decreased use of rescue medications, and improved peak expiratory flow rate, compared to ipratropium. Tiotropium also resulted in fewer hospital admissions, fewer inpatient hospital days, and fewer unscheduled visits. Tiotropium was compared to salmeterol, and found to be more effective than salmeterol in regards to improved evening peak expiratory flow, all cause hospital admission rate, and unscheduled physician visits. Due to tiotropium's narrow indication for bronchospasm associated with COPD, there is not a role for tiotropium in general use. Although tiotropium may offer benefits for some patients with COPD, use for special needs/circumstances as such, can be established with medical justification, through the prior authorization process. Therefore, all brands within the class are comparable to each other and to the generics in the class and offer no significant advantage over other alternatives in general use. No brand of tiotropium was recommended for preferred status. Dr. Clark confirmed whether Spiriva was the only once daily bronchodilator and explained patients with COPD can benefit from this medication. Dr. Holloway agreed with Dr. Clark. Dr. Magouirk commented tiotropium is appropriate for use in stage 2 disease, but is not for all patients with mild disease, and didn't think tiotropium should be a preferred agent. There was discussion among the board as to prior authorization criteria for the drug. Dr. Feldman reiterated that once daily treatment is important as well as the evidence on decreasing hospital visits. Dr. A.Z. Holloway motioned to amend the recommendation to place tiotropium as a preferred agent on the Alabama Medicaid preferred drug list.

Richard Freeman asked the board to mark their ballots.

**Amlodipine/atorvastatin (Caduet) AHFS Class 240608**
Manufacturer comments on behalf of these products:
Caduet

Janelle Sheen discussed the clinical data on the combination agent amlodipine/atorvastatin. The combination is indicated for patients in whom treatment with both atorvastatin and amlodipine are appropriate. This includes hypercholesterolemia, elevated triglyceride levels, primary dysbetalipoproteinemia, homozygous familial hypercholesterolemia, hypertension, chronic stable angina, and vasospastic angina. The drug is dosed once daily with the same dosing recommendations as for each single entity agent. The efficacy and safety of the combination agent is similar to the individual agents administered separately. No studies have evaluated the efficacy of amlodipine/atorvastatin to amlodipine and atorvastatin monotherapies administered concomitantly. The combination has no clinical advantage over amlodipine and atorvastatin when administered separately in respect to blood pressure reduction achieved with amlodipine and LDL-C lowering achieved with

atorvastatin. Therefore, atorvastatin/amlodipine (Caduet) is comparable to the drugs in this class and to the generics and OTC products and offers no significant clinical advantage over other alternatives in general use. No brand of the combination atorvastatin/amlodipine (Caduet) was recommended for preferred status. Dr. Feldman asked about the cost of the combination agents versus that of the separate agents, and Louise Jones reminded the board cost was not a consideration. Dr. Holloway questioned whether either agent was available as a generic and was told neither agent was available in a generic formulation.

Richard Freeman asked the board to mark their ballots.

(8) ANTIDEPRESSANT WARNING UPDATE

Janelle Sheen discussed that the FDA recommended a black box warning for all antidepressants. The update was announced on October, 15, 2004, a week after the binders were printed and mailed, so the information in the binder is not up to date. Janelle gave a verbal update which included the following information. The recommendation from the FDA directed all manufacturers of antidepressant drugs to revise labeling for their products to include a boxed warning and expanded warning statements. Statements should alert healthcare providers to an increased risk of suicidality in children and adolescents being treated with antidepressants, and to include additional information about results of pediatric studies. In twenty-four pediatric studies of over 4,400 patients, there was a greater risk of suicidality during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug therapy was 4%, or twice the placebo risk 2%.

Statements included in the boxed warning include:

- Antidepressants increase the risk of suicidal thinking and behavior in children and adolescents with major depressive disorder and other psychiatric disorders.
- Anyone considering use of an antidepressant in a child or adolescent for any clinical use, must balanced the risk of increased suicidality with the clinical need for the drug.
- Patients started on therapy should be advised to closely observe the patient and to communicate with the prescriber.
- A statement regarding whether the particular drug is approved for any pediatric indication (s) and if so, which ones.

The FDA also recommended use of Patient Medication Guides, to inform patients with the proper safety information in a user friendly manner. MedGuides are intended to be distributed by pharmacists with each antidepressant fill or refill. The FDA also intends to work with manufacturers to implement "Unit of Use" packaging for all antidepressants as a means of ensuring that patients receive the MedGuide with every prescription refill. Dr. Feldman discussed with the board, that although there is increased suicidal ideation with these drugs, there are patients who greatly benefit from antidepressants. She explained she did not feel

in favor of the black box as it will likely prevent patients from being treated, and from getting needed benefit from antidepressants. Dr. Feldman also added that the FDA's recommendation for proper monitoring of patients on antidepressants is strict and she is worried about this impact on the Medicaid population (e.g. limited physician visits). Dr. Feldman also felt at this time there isn't anything the board needs to do, except determining if increasing visits for pediatrics is necessary. Dr. Freeman commented some pediatric physicians are hesitant to prescribe these drugs, and it may have an impact on the number of patients referred to specialty mental health services (e.g. psychiatrist).

(9) RESULTS OF VOTING

Louise Jones announced the results of voting for each of the therapy classes. Results of voting are described in section twelve of the minutes.

(10) NEW BUSINESS

A.Z. Holloway asked about prior authorization of Pulmicort, and the topical immunomodulators. He explained it appeared his requests for these agents were always approved and questioned if the requests are always approved, then what is the role of having these agents available through prior authorization? Dr. McIntyre explained even though it might appear all of Dr. Holloway's requests are being approved, requests from other physicians (non-pediatricians) are not always being approved, and for that matter, the criteria in place are doing their job and would need to stay in place. She also added that electronic prior authorization would help with paperwork, for any of the criteria that could pull from diagnosis codes, etc. Dr. Holloway also asked if the Agency was getting offers from manufacturers who didn't initially make supplemental rebate offers and Louise Jones commented that the new quarter started October 1 and they are continuing to receive offers as manufacturers see their market share decrease. Louise advised that manufacturers need to have all rebate offers in to the agency by December 1, 2004 to be considered for the next PDL update.

Louise Jones discussed that for the first time, members (pharmacists and physicians) of the P&T board have available to them continuing education for attending the meeting. The board thanked Dr. Searcy for his hard work at making this happen. Dr. Searcy asked that each member complete the proper paperwork. Louise Jones asked members to also complete their travel vouchers.

(11) CLOSING REMARKS

The next P&T meeting will be held on January 26, 2004 at 1:00 p.m. Richard Freeman adjourned the meeting at 4:28p.m.

(12) RESULTS OF THE BALLOTING

A. The P&T Committee voted unanimously to accept the recommendation that no brand anthelmintic is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

| | | | |
|---|---|---|---|
| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

B. The P&T Committee voted unanimously to accept the recommendation that no brand aminoglycoside is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

C. The P&T Committee voted unanimously to accept the recommendation that no brand antifungal is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

D. The P&T Committee voted unanimously to accept the amended recommendation that at least one brand third generation cephalosporin oral suspension be preferred, and that Rocephin (ceftriaxone) be placed in preferred status until a generic formulation is available. Medicaid should accept cost proposals from the manufacturers of third generation cephalosporin suspensions to determine cost effective products and designate at least one brand as a preferred agent. Medicaid should place Rocephin in preferred status on the Preferred Drug List.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

E. The P&T Committee voted unanimously to accept the recommendation that no single entity miscellaneous B-lactam antibiotic is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

F. The P&T Committee voted unanimously to accept the recommendation that no brand combination miscellaneous B-lactam antibiotic is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

G. The P&T Committee voted unanimously to accept the recommendation that no brand of chloramphenicol is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

H. The P&T Committee voted unanimously to accept the recommendation that no brand single entity penicillin is recommended for preferred status. Medicaid should accept cost proposals from the manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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|---|---|---|---|
| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

I. The P&T Committee voted unanimously to accept the recommendation that no brand combination penicillin antibiotic is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

J. The P&T Committee voted seven (approve as recommended) to one (disapprove) to accept the recommendation that no brand tetracycline is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

K. The P&T Committee voted unanimously to accept the recommendation that no brand antiviral single entity nucleoside/nucleotide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

L. The P&T Committee voted seven (approve as recommended) to one (disapprove) to accept the recommendation that in the Misc. antiviral class, no brand of foscarnet is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

M. The P&T Committee voted seven (approve as recommended) to one (no action) to accept the recommendation that no brand amebicide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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|---|---|---|---|
| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

N. The P&T Committee voted seven (approve as recommended) to one (no action) to accept the recommendation that no brand single entity antimalarial product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

O. The P&T Committee voted seven (approve as recommended) to one (no action) to accept the recommendation that no brand combination antimalarial agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

P. The P&T Committee voted seven (approve as recommended) to one (no action) to accept the recommendation that no brand antiprotozoal is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

Q. The P&T Committee voted six (approve as recommended) to 1 (disapprove), to 1 (no action), to accept the recommendation that no brand combination estrogen transdermal product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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|---|---|---|---|
| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

R. The P&T Committee voted unanimously to accept the recommendation that no brand of olanzapine/fluoxetine (Symbyax) is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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|---|---|---|---|
| Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

S. The P&T Committee voted unanimously to accept the recommendation that no brand of paroxetine mesylate (Pexeva) is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

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| John Seavey<br>Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Kathy Hall<br>Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

T. The P&T Committee voted two (approve as recommended) to six (approve as amended) to accept the amended recommendation that tiotropium (Spiriva) be placed in preferred status. Medicaid should place tiotropium (Spiriva) in preferred status on the Preferred Drug List.

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|---|---|---|---|
| John Seavey<br>Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Kathy Hall<br>Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

U. The P&T Committee voted six (approve as recommended) to two (disapprove) to accept the recommendation that no brand of the combination atorvastatin/amlodipine (Caduet) is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

| | | | |
|---|---|---|---|
| John Seavey<br>Medical Director | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Kathy Hall<br>Deputy Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |
| Commissioner | ☑ Approve | ☐ Deny | ☐ Approve with modification |

Respectfully submitted.

Janelle Sheen — 11-4-2004

Janelle Sheen — Date